# CONAZOL- miconazole nitrate cream Laboratorios Liomont, S.A. de C.V.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### **Conazol Cream**

#### **Active Ingredient**

Miconazole nitrate 2%

#### **Purpose**

Antifungal

#### Uses

- effective in the treatment of most athlete's foot, jock itch and ringworm
- relieves itching, cracking, burning and discomfort associated with these conditions

#### **Warnings**

#### For external use only

#### Do not use

on children less than 2 years of age unless directed by a doctor

#### When using this product

• avoid contact with the eyes

#### Stop use and ask a doctor if

- irritation occurs
- there is no improvement of athlete's foot or ringworm within 4 weeks or jock itch within 2 weeks

#### Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- wash the affected area and dry thoroughly
- apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor
- supervise children in the use of this product
- for athlete's foot, pay special attention to the spaces between the toes; wear well-fitting, ventilated shoes, and change shoes

#### and socks at least once daily

• for the athlete's foot and ringworm, use daily for 4 weeks

- for jock itch, use daily for 2 weeks
- not effective on the scalp or nails

## Other Information

• store at 20° to 25°C (68° to 77°F)

## **Inactive Ingredients**

butylated hydroxyanisole, caprylic/capic triglyceride,carbomer 980, emulsifying wax, glycerin, methylparaben, propylene glycol, propylparaben, purified water, triethanolamine

## **Package Label**



miconazole nitrate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59208-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MICO NAZO LE NITRATE (UNII: VW4H1CYW1K) (MICONAZO LE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g		

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
GLYCERIN (UNII: PDC6A3C0OX)		
METHYLPARABEN (UNII: A218 C7H19 T)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
TROLAMINE (UNII: 903K93S3TK)		

ı	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 NDC:59208-001-30	30 g in 1 TUBE; Type 0: Not a Combination Product	03/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/01/2019	

## Labeler - Laboratorios Liomont, S.A. de C.V. (810347807)

Establishment			
Name	Address	ID/FEI	Business Operations
Laboratorios Liomont, S.A. de C.V.		810347807	manufacture(59208-001)